ASTRALIS LTD
Form 10KSB
April 21, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

(Mark One)

|X| ANNUAL REPORT UNDER SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2005

|_| TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from ___ to ___
Commission File Number: 000-30997

ASTRALIS LTD.
(Name of Small Business Issuer in its Charter)

| Delaware | 84-1508866 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 75 Passaic Avenue, Fairfield, New Jersey | 07004 |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (973) 227-7168

Securities registered pursuant to Section 12(b) of the Act:

| Title of Each Class | Name of Each Exchange on Which Registered |
|---|---|
| None. | None. |

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $.0001 per share
(Title of Class)

Check whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes |_| No |X|

Check whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 ("Exchange Act") during the past 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days: Yes |X| No |_|

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Check mark if no disclosure of delinquent filers pursuant to Item 405 of Regulations S-B is not contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in a definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. |_|

Indicate by check mark whether the registrant is a shell company as defined in Rule 12b-2 of the Exchange Act. |_|

Issuer's revenue for the year ended December 31, 2005: $0

As of March 31, 2006, the aggregate market value of the voting and nonvoting common stock held by nonaffiliates of the registrant was approximately $3,457,486.

As of March 31, 2006, there were 91,454,873 shares of the issuer's common stock outstanding.

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PART I

Item 1. Description of Business

General

Astralis, Ltd. ("Astralis", "we", "us", "our", or the "Company") is a development stage biotechnology company engaged primarily in the research and development of treatments for immune system disorders and skin diseases, such as psoriasis and psoriatic and rheumatoid arthritis. The Company's initial product candidate, Psoraxine(R), is a protein extract used for the treatment of the skin disease psoriasis.

Currently, the Company is engaged in the following activities to further its development efforts of its initial product candidate:

- Ongoing research and development of Psoraxine(R);
- Recommencing clinical trials to obtain the approval of the United States Food and Drug Administration for the marketing of Psoraxine(R); and
- Developing technology underlying Psoraxine(R) for the treatment of indications other than psoriasis, such as arthritis, eczema, seborrheic dermatitis and leishmaniasis.

The Company was originally incorporated under the laws of the State of Colorado in 1999 under the name Hercules Development Group, Inc. We subsequently changed our name to Astralis Pharmaceuticals Ltd. and, in November 2001, reincorporated under the laws of the State of Delaware under our present name. Our main office is located at 75 Passaic Avenue, Fairfield, New Jersey 07004.

Recent Developments

Blue Cedar March 2006 Private Placement

On March 31, 2006, the Company closed a private placement of securities

from which it received proceeds of $250,000. In connection with this private placement, the Company issued to Blue Cedar Limited ("Blue Cedar"), an accredited investor and currently a stockholder of the Company, (i) a convertible promissory note in the principal amount of $250,000, convertible into shares of the Company's common stock at $0.09 per share, and (ii) a warrant to purchase 2,777,778 shares of common stock. Lipworth Capital Limited acted as the placement agent in connection with the private placement. The securities offered and sold in this private placement were sold in reliance on an exemption from the registration requirements under Regulation D of the Securities Act of 1933, as amended (the "Securities Act").

Departure of Directors and Principal Officer

On December 11, 2005, Steven Fulda, a member of the Board of Directors and Audit Committee of the Company, announced his resignation from the Board and Audit Committee, effective December 30, 2005. Mr. Fulda's announcement did not reference a disagreement with the Company on any matter relating to the Company's operations. In addition, on April 19, 2006 Fabien Pictet announced that he will be resigning as a member of the Board of Directors of the Company. Mr. Pictet has not yet announced an effective date of his resignation, nor did his announcement reference a disagreement with the Company on any matter relating to the Company's operations.

On January 25, 2006, James Sharpe resigned as a member of the Board of Directors, Chief Executive Officer and President of the Company, pursuant to a Separation Agreement and General Release, by and between the Company and Mr. Sharpe ("Separation Agreement"). Mr. Sharpe, whose resignation was effective as of December 31, 2005, did not resign due to a disagreement with the Company on any matter relating to the Company's operations. Michael Garone, the Company's Chief Financial Officer, currently is serving as the Company's interim President until the Company's Board of Directors elects a new Chief Executive Officer and President to replace Mr. Sharpe.



Limited Working Capital

As of April 15, 2006 we have $277,705 in available cash and accounts payable of $65,067. Based on our current plans, we believe the Company has sufficient funds to meet our operating expenses and capital requirements only through approximately May 2006. We will need to raise additional funds to continue our operations following that period. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine(R), especially given the failure of our Phase II study to meet its primary endpoint.

Psoriasis

Psoriasis is a chronic inflammatory skin disorder of currently unknown origins that generally lasts a lifetime and for which there is presently no known cure. Researchers believe that psoriasis may be caused by the immune system sending faulty signals that affect the growth cycle of skin cells. As a result, skin cells accumulate on the surface of the body faster than normal. In people without psoriasis, skin cells mature and are shed approximately every 28 days. In psoriatic skin, the skin cells mature over a period of approximately three to six days.

The symptoms of psoriasis include scaly skin and inflammation occurring on a cyclical basis, with periods of remission and relapse. There are five types of

psoriasis. The most common form, appearing in approximately 80% of individuals suffering from the disease, is plaque psoriasis. The other forms are guttate, inverse, erythrodermic and pustular psoriasis. Psoriasis typically does not prevent individuals with the condition from functioning normally. However, the pain, discomfort and emotional effects may be extensive.

Market Opportunity

According to the National Psoriasis Foundation, psoriasis affects approximately 2.1% of the United States population, or more than 4.5 million people in the United States. Psoriasis also affects approximately 1% to 3% of the world's population. Approximately 150,000 to 260,000 new cases of psoriasis are diagnosed each year. In addition, each year approximately 350 people in the United States die due to complications caused by psoriasis. Primarily, such complications occur in relation to severe, extensive forms of psoriasis such as erythrodermic or pustular psoriasis, where large areas of skin are shed. Because the skin plays an important role in regulating body temperature and serving as a barrier to infection, when a person's skin is severely compromised, secondary infections may occur. These serious forms of psoriasis may also cause complicating factors, such as fluid loss and strain on the circulatory system.

The National Psoriasis Foundation also indicates that between 10% and 30% of people who have psoriasis will also develop psoriatic arthritis, which is similar to rheumatoid arthritis, but generally milder. Psoriatic arthritis causes inflammation and stiffness in the soft tissue around joints, and frequently affects the fingers and toes. Psoriatic arthritis may also affect other areas of the body such as the wrists, neck, lower back, knees and ankles.

Psoriasis is a chronic illness that, in many cases, requires continuous treatment. Patients with psoriasis often pay for costly medications and face ongoing visits with physicians. Severe cases may require periods of hospitalization. The National Psoriasis Foundation estimates that the costs of treating psoriasis may exceed $3.0 billion annually.



Psoraxine(R)

Psoraxine(R) was developed by Dr. Jose Antonio O'Daly, our Chairman of the Board and Chief Scientific Officer. In 1991, Dr. O'Daly was conducting trials for a vaccine for leishmaniasis in Caracas, Venezuela. One patient involved in the leishmaniasis vaccine trials, who also suffered from psoriasis for 12 years, experienced complete remission of psoriasis after receiving the vaccine. As a result of this discovery, Dr. O'Daly focused his efforts on developing a product for the treatment of psoriasis. From 1992 through 2001, Dr. O'Daly developed Psoraxine(R), a purified version of the original product that is an immunotherapeutic agent presented in liquid form and packed in 0.5 milligram ampules for intra-muscular injection. Dr. O'Daly tested the original product that was a precursor of Psoraxine(R) in approximately 2,900 patients in several clinical trials in Venezuela. The results from the studies provided evidence of remission of psoriasis lesions as a result of treatment with the product. In addition, individuals in the studies did not present severe side effects as a result of treatment. In one clinical study, of the 2,770 patients, 648, or 28%, experienced complete remission of psoriasis. In addition, almost half of the patients experienced psoriasis reduction of between 70% to 99% as measured by the Psoriasis Area and Severity Index ("PASI"). Additional studies yielded average PASI reductions of between 73% and 92%.

Dr. O'Daly licensed Psoraxine(R) to us in 2001 and moved to the United States in 2002. We made capital investments to our research and development

facility of approximately $500,000 in 2002 and we filed an Investigational New Drug application with the FDA for Psoraxine(R) in March 2003. On August 4, 2003 the FDA allowed us to commence our Phase I clinical trials for Psoraxine(R).

The purpose of Phase I studies is to test the safety of a drug. We have completed our Phase I studies, which involved the administration by intramuscular injection of a single dose of 50, 150 or 300 micrograms of Psoraxine(R) or a placebo in a controlled setting to groups of psoriatic patients. Our Phase I results indicate that Psoraxine(R) is safe and well-tolerated. We spent approximately $130,000 on our Phase I studies in 2003 and approximately $210,000 on our Phase I studies in 2004.

We commenced Phase II studies in April 2004. The purpose of Phase II studies is to test the safety and efficacy of a drug. The Phase II studies have been completed. We spent approximately $2,150,000 on our Phase II studies in 2004. The initial analysis of the preliminary data from the Phase II studies indicated that treatment with Psoraxine(R) did not provide any statistically significant clinical improvement of psoriasis in participants of the studies. We are continuing to analyze the data from the Phase II studies to understand why statistical significance at its primary endpoint was not achieved and to evaluate our clinical development options for Psoraxine(R). We spent $1,635,461 during fiscal year 2005 to complete Phase II studies. For the year ended December 31, 2005, we reflected $2,510,521 in research and development expenses which included $114,976 to record the impairment of an intangible asset. For the year ended December 31, 2004, we reflected $7,689,060 in research and development expenses, including $4,519,400 related to SkyePharma.

Current Psoriasis Therapies

The topical treatment for psoriasis has been based on the use of emollients, keratolytic agents, coal tar, anthralin, corticosteroids of medium to strong potency and calcipotriene. UVB phototherapy has been used in the treatment of moderate cases of psoriasis. For severe cases, systemic treatments include methotextrate, cyclosporine and oral retinoids. Each of these treatments has variable efficacy, with side effects and cosmetic problems in addition to the failure to prevent frequent relapses.



Competition and Psoriasis Treatments in Development

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in activities similar to ours, including research and development of drugs for the treatment of the same disease as Psoraxine(R). The FDA has approved Amevive, manufactured by Biogen, Raptiva, manufactured by Genentech/Xoma, and Enbrel, manufactured by Amgen and Wyeth, for the treatment of moderate-to-severe chronic plaque psoriasis in adult patients. If we succeed in obtaining FDA approval of Psoraxine(R), Amevive, Raptiva and Enbrel may compete directly with our product. In addition to Biogen, Genentech/Xoma, Amgen and Wyeth, our competitors may include Centocor, Abbott Laboratories and Novartis. Many of these companies have substantially greater financial and other resources, larger research and development staffs, and more extensive marketing and manufacturing organizations than we have. In addition, these companies have more experience in preclinical testing, clinical trials and other regulatory approval procedures than we have. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also come to develop and market commercial products, either on their own or through collaborative efforts.

We expect to encounter significant competition for any of the pharmaceutical products we develop. Companies that complete clinical trials obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage.

Developments by others may render our product obsolete or noncompetitive. We will face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to additional technologies. These competitors may succeed in developing technologies or products that are more effective than Psoraxine(R).

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our potential products.

The process required by the FDA before our product candidate, Psoraxine(R), may be marketed in the United States generally involves the following:

- preclinical laboratory and animal tests;
- submission of an Investigational New Drug application, which must become effective before clinical trials may begin;
- adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- FDA approval of a new drug application or biologics license application.



The testing and approval process requires substantial time, effort and financial resources, and there can be no assurance that any approvals for Psoraxine(R) or any other potential products will be granted on a timely basis, if at all.

Prior to commencing clinical trials, which are typically conducted in three sequential phases, a company must submit an Investigational New Drug application to the FDA. In March 2003, we filed our Investigational New Drug application for Psoraxine(R) with the FDA. The Investigational New Drug application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trial. In such a case, the Investigational New Drug sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. In August 2003, the FDA informed us that we could commence our clinical trials of Psoraxine(R). We have completed Phase I clinical trials in which Psoraxine(R) was found to be generally safe and well-tolerated in Phase I test patients. We also completed 12 months ago a Phase II clinical trial, which did not achieve its primary endpoint for PASI (Psoriasis Area and Severity Index) reduction. We are continuing to analyze the data collected during the Phase II study, including biopsy data indicating cellular level changes that has

not been previously available, to gain a better understanding of the results, and to direct our future efforts.

Although we remain committed to the future clinical development of Psoraxine(R), we may not successfully complete the three phases of clinical trials of Psoraxine(R) within any specific time period, if at all. Furthermore, the FDA or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a new drug application or biologics license application. The FDA may deny a new drug application or biologics license application if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data is submitted, the FDA may ultimately decide that the new drug application or biologics license application does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or indication. Government regulation may delay or prevent marketing of potential products or new indications for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials.

Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, additional regulatory approvals for any of our product candidates would have a material adverse effect on our business.



Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with good manufacturing practices, which impose certain procedural and documentation requirements upon us and any third party manufacturers we may utilize. We cannot be certain that our present or future suppliers will be able to comply with the good manufacturing practices, regulations and other FDA regulatory requirements.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to

country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union, registration procedures are available to companies wishing to market a product in more than one EU Member State. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA clearance. To date, we have obtained regulatory approval for clinical testing of Psoraxine(R) in Venezuela, but we have not obtained final regulatory approval for commercial distribution of Psoraxine(R) in Venezuela because we do not have manufacturing facilities in that country and such facilities are required by regulatory authorities in Venezuela before granting commercial approval for a proposed drug.

Intellectual Property

In January 2004 the United States Patent and Trademark Office ("PTO") issued a patent to Dr. Jose O'Daly for the "Compositions and Methods for the Treatment and Clinical Remission of Psoriasis." Under the terms of a license agreement and assignment of license agreement, we have the exclusive right and license to use and exploit this patent. Dr. O'Daly will continue to maintain ownership rights with respect to the patent and patent application. However, Dr. O'Daly has granted us a perpetual, royalty free license to his patent under the agreements, which will terminate only upon the expiration of the patent, or upon the commencement of a bankruptcy or insolvency proceeding involving our company or upon our dissolution or liquidation.

In March 2002, Akiva LLC, an entity controlled by Dr. O'Daly, also filed an application to obtain patent protection internationally under the Patent Cooperation Treaty. In addition, in August 2003, Akiva LLC filed patent applications in the European Union, Australia, Brazil, Canada, Mexico and Japan. We have rights to these applications, which are currently pending, pursuant to the license and assignment of license agreements described above.

In January 2004, Dr. O'Daly filed a patent application with the PTO focusing on the mechanism of action of Psoraxine(R), expanding the claims to include medical indications other than psoriasis, such as Atopic Dermatitis, Psoriatic Arthritis and Rheumatoid Arthritis. In addition, the patent elaborates further on the mechanism of action of Leishmania extracts, which are believed to induce T-cell activation. In January 2004, Dr. O'Daly also filed a second patent relating to a culture medium for parasitic organisms, which is part of our technology platform. Dr. O'Daly has assigned to us the rights in the patent applications. Also, in January 2004, the PTO granted us a federal trademark registration for the mark Psoraxine(R).



Agreements with SkyePharma

We entered into a Purchase Agreement dated as of December 10, 2001 with SkyePharma PLC ("SkyePharma") pursuant to which SkyePharma purchased an aggregate of 2,000,000 shares of our Series A Convertible Preferred Stock, par value $.001 per share ("Series A Preferred Stock"), for an aggregate purchase price of $20.0 million. On January 20, 2004, pursuant to our Omnibus Conversion Agreement with SkyePharma, dated January 12, 2004, SkyePharma converted all of its 2,000,000 shares of our Series A Preferred Stock into 25,000,000 shares of our common stock at a conversion price of $0.80 per share. In March 2005, SkyePharma also acquired an additional 11,160,000 shares of our common stock in a privately negotiated transaction with two private holders. As a result, SkyePharma beneficially owned 49.8% of our common stock at that time. During August 2005, the Company closed on an investment of $2 million. Consequently

SkyePharma's share of beneficial ownership was approximately 39.7% on December 31, 2005. Additionally, during March 2006, the Company closed on an investment of $250,000. Consequently SkyePharma's share of beneficial ownership is now approximately 39.8%.

On January 20, 2004, in connection with SkyePharma's conversion of the Series A Preferred Stock, we entered into a Call Option Agreement with SkyePharma, pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the $0.80 conversion price. In the event we exercise the call option, the exercise price will be between $1.28 and $1.52 per share, depending on the date of exercise. The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007. In June 2004, we assigned the right to purchase 1,250,000 shares under the Call Option Agreement to FPP Capital Advisors as consideration for services it provided in negotiating the Omnibus Conversion Agreement. FPP Capital Advisors is controlled by Fabien Pictet, a member of our Board of Directors.

On January 20, 2004, the closing date of the conversion of SkyePharma's 2,000,000 shares of our Series A Preferred Stock, we, SkyePharma and our other original shareholders amended the Stockholders' Agreement, dated as of December 10, 2001 (the "Amended SkyePharma Stockholders' Agreement"). Pursuant to the Amended SkyePharma Stockholders' Agreement, our board of directors is required to be comprised of at least seven directors and must include at least two independent directors. Per the Amended SkyePharma Stockholders' Agreement, SkyePharma has the right to nominate one director. Michael Ashton is SkyePharma's initial and current nominated director. Until January 20, 2007, Jose Antonio O'Daly has the right to nominate one Director. The Amended SkyePharma Stockholders' Agreement will terminate upon the later of (i) the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock or (ii) January 20, 2007. Further, the Amended SkyePharma Stockholders' Agreement may be terminated by the mutual written consent of the parties. Pursuant to the Amended SkyePharma Stockholders' Agreement, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions that have been approved by our board of directors and all of our independent directors. These transactions include (i) the amendment of our certificate of incorporation solely to increase our authorized capital stock, (ii) the adoption or amendment of an employee benefit plan applicable to all employees, (iii) the issuance of additional securities for cash and (iv) the sale of all of our outstanding capital stock or all or substantially all of our assets, or our merger with another entity, provided that SkyePharma will receive the same consideration for its shares as other holders of common stock and will be able to participate in the sale or merger on the same terms as the most favorable terms available to any of our other stockholders and the total consideration for the transaction is greater than $135 million.



We also entered into two agreements concerning the formulation and development of our initial injectable product candidate, Psoraxine(R), with SkyePharma. Under the terms of the Technology Access Option Agreement, dated December 10, 2001, we paid to SkyePharma a $5.0 million technology access fee for the option to acquire a license for DepoFoam and other relevant drug delivery technologies owned by SkyePharma. Under the terms of the Technology Access Option Agreement, if we exercise our option, we must pay a royalty of 5% of net sales of all products manufactured or sold that use or exploit the drug delivery technologies that we license from SkyePharma. In addition, if we exercise our option, SkyePharma retains the right during the term of the Technology Access Option Agreement to undertake the manufacture of all of our

products that incorporate or utilize the drug delivery technologies. The option we received under the Technology Access Option Agreement expires on December 10, 2008. The Technology Access Option Agreement may be terminated by either party if (i) the other party commits any irremediable breach of the agreement, (ii) the other party commits any remediable breach and fails to remedy such breach within sixty days of service of notice of the breach, (iii) a court makes an administration order with respect to the other party or any composition in satisfaction of the debts of, or scheme of arrangement of the affairs of, the other party, or (iv) the other party becomes insolvent, has a receiver appointed over any of its assets, enters into any composition with creditors generally or has an order made or resolution passed for it to be wound up. SkyePharma has the right of first negotiation to acquire the worldwide marketing rights to Psoraxine(R). We have evaluated the technology access option fee we paid under the Technology Access Option Agreement, which we have been capitalizing as a research and development intangible asset over a seven-year period, and have determined that as of December 31, 2004, the technology access option fee exceeded its fair market value. Consequently, we recorded as additional research and development costs in 2004 a charge of $2,797,612 to reflect an impairment of this intangible asset.

In addition, we entered into a Service Agreement, dated December 10, 2001, pursuant to which SkyePharma was to provide us with development, manufacturing, pre-clinical and clinical development services in consideration of $11 million, of which $3 million was paid in 2001, with the remaining $8 million paid primarily during 2002 for second generation Psoraxine(R). The Service Agreement terminated on December 31, 2002. We entered into an Amendment to the Service Agreement with SkyePharma, effective as of January 1, 2003, to extend the term of the Service Agreement and modify the services to be provided by SkyePharma such that SkyePharma continued to provide certain services to us through December 31, 2004, in consideration for payments made during 2002. The agreement expired on December 31, 2004.

Blue Cedar August 2005 Private Placement

On August 19, 2005, we completed a private placement of securities from which we received gross proceeds of approximately $2,000,000. The transaction consisted of the sale to one accredited investor, Blue Cedar, of units consisting of: (i) 18,181,818 shares of common stock, (ii) warrants to purchase over a 5-year period 18,181,818 shares of common stock with an exercise price of $0.165 and (iii) warrants to purchase over a 12-month period 12,121,212 shares of common stock with an exercise price of $0.165. We relied upon the exemption from registration provided under Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. The private placement was only made available to one "accredited investor" as defined in Rule 501 of Regulation D. Lipworth Capital Limited acted as our placement agent in connection with the private placement. We paid an 8% fee to our placement agent and issued warrants to purchase 1,454,545 shares of common stock with an exercise price of $0.165, in connection with the financing in addition to other costs. Additionally, we granted Blue Cedar certain registration rights pursuant to a registration rights agreement, dated as of August 17, 2005, in connection with this transaction. The registration rights agreement required us to file a registration statement within approximately 30 days of the final closing of our private placement covering the resale of all shares included therein, as well as the shares underlying the warrants. Because a registration statement covering the resale of such shares was not filed or effective by December 31, 2005, the date specified in the agreement, we are subject to liquidated damages payments of $10,000 per month, being 0.5% of the aggregate purchase price plus 10% interest per annum to be paid on unpaid liquidated damages amounts until such time as a registration statement covering the resale of securities sold to Blue Cedar is declared effective by the Securities and Exchange Commission.

Concurrently with the closing of the private placement, we and Blue Cedar entered into the Blue Cedar Stockholder's Agreement. Pursuant to the Blue Cedar Stockholder's Agreement, our Board of Directors is required to be comprised of at least eight directors and Blue Cedar may designate one director to our Board of Directors. Manuel Tarabay is Blue Cedar's initial and current designated director. Further, pursuant to the Blue Cedar Stockholder's Agreement, we agreed not to enter into any service agreement, distribution arrangement or transfer of personnel with any of our stockholders owning more than 10% of the outstanding shares of common stock until we complete Phase II clinical trials of Psoraxine(R), without the prior written consent of Blue Cedar, which shall not be unreasonably withheld. Additionally, for a period of two years following the closing date of the private placement, we granted Blue Cedar certain pre-emptive rights, allowing Blue Cedar to participate in substantially all sales of securities. The Blue Cedar Stockholder's Agreement will terminate upon the earlier of the Blue Cedar Termination Date or August 15, 2008. The "Blue Cedar Termination Date" is the date on which Blue Cedar no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock.

Other Research and Development Efforts

In addition to our development of Psoraxine(R) for the treatment of psoriasis, we are researching its possible application for the treatment of other conditions, such as eczema, seborrheic dermatitis and leishmaniasis. We are also developing a second product for the treatment of arthritis. We intend to market this product primarily in the United States, although we have not named this product yet and we do not have any approvals from, nor has any application been filed with, the FDA or any foreign governmental regulatory authority for this product. Currently, we do not have any collaborators for this product. We are also engaged in preliminary research of a treatment for transplant rejection.

Employees and Consultants

As of March 31, 2006, we employed five full-time employees, including three scientists and one laboratory technician. We also have seven consultants. We have no part-time employees. None of our employees are covered by a collective bargaining agreement and we believe that our employee relations are good.

## FORWARD-LOOKING STATEMENTS

This annual report on Form 10-KSB contains many forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as "may", "will", "expect", "anticipate", "believe", "estimate", and "continue" or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future operating results or of our financial condition or state other "forward-looking" information.

We believe that it is important to communicate our future expectations to our investors. However, we may be unable to accurately predict or control events in the future. The factors listed in the sections captioned "Risk Factors" and "Management's Discussion and Analysis or Plan of Operation", as well as any other cautionary language in this annual report, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described in the "Risk Factors" section, the "Management's Discussion and Analysis or Plan of Operation" section and elsewhere in this annual report could

seriously harm our business.



RISK FACTORS

You should carefully consider each of the following risk factors and all of the other information in this report. The following risks relate principally to the Company's business. If any of the following risks actually occur, the business, financial condition or results of operations of the Company could be materially adversely affected. As a result, the market price of shares of the Company's common stock could decline significantly.

We will need to obtain additional funds immediately to support our future operation expenses. Our auditors have expressed uncertainty regarding our ability to continue as a going concern.

As of April 15, 2006 we have $277,705 in available cash and accounts payable of $65,067. Based on our current plans, we believe that we have sufficient funds to meet our operating expenses and capital requirements through approximately May 2006. We will need to raise additional funds to continue our operations following that period. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine(R), especially given the failure of our Phase II study to meet its primary endpoint. No assurance can be given that we will be able to obtain financing, or successfully sell assets or stock, or, even if such transactions are possible, that they will be on terms reasonable to us or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders. If we do not obtain additional funds, we will likely be required to eliminate programs, delay development of our products, alter our business plans, or in the extreme situation, cease operations.

As a result of our losses and the matters described in the preceding paragraph, the Independent Auditors' Report on our financial statements includes a paragraph indicating doubt about our ability to continue as a going concern. The financial statements that accompany this report do not include any adjustments that might be necessary if we are unable to continue as a going concern.

We have no sales; we will not have sales in the foreseeable future; we are in an early stage of development and we may never sell products or become profitable.

We commenced our current operations in 2001 and such operations remain in an early stage of development. We have no products approved for sale and therefore, no means to generate revenue. We have not commercialized any products, had no revenues and had incurred a cumulative net loss of $53,616,516 as of December 31, 2005 which has increased to date. The cumulative net loss through December 31, 2005 includes non-cash preferred stock dividends of $22,218,750. We expect that substantial losses will continue for the foreseeable future. In order to obtain revenue from the sales of our product candidate, Psoraxine(R), we must successfully develop, test, obtain regulatory approval for, manufacture, market and eventually sell such product candidate. Our expenses have consisted principally of costs incurred in research and development and from general and administrative costs associated with our operations. We expect our expenses to increase and to continue to incur operating losses for the next several years as we continue our research and development efforts for Psoraxine(R) and any subsequent product candidates.

Commercialization of any of our products will take a significant amount of time and successful commercialization may not occur at all. As a result, we may never become profitable.

Psoraxine(R) may never be approved by the FDA because the results of our Phase II study failed to meet its primary study endpoint.



We have focused our development efforts to date on conducting clinical trials for an immuno-stimulatory drug, Psoraxine(R), for the treatment of psoriasis. We recently conducted a randomized, double-blinded, placebo-controlled clinical study involving 120 patients with moderate to severe psoriasis who received six (6) intramuscular injections of Psoraxine(R). The primary endpoint of the study was a specified level of improvement of symptoms measured in accordance with the Psoriasis Area and Severity Index, or PASI, which is a measurement scale that ranks the severity of symptoms of patients suffering from psoriasis. Our initial analysis of the preliminary data showed no statistically significant improvement of those Phase II study patients who received six injections of Psoraxine(R) for a twelve weeks treatment period compared to patients taking a placebo.

The failure of our Phase II study to meet its primary endpoint makes FDA approval of Psoraxine(R) substantially more uncertain. To continue Psoraxine(R) 's development and to obtain FDA approval to market Psoraxine(R), we must complete our analysis of the data from the Phase II study to identify why the Phase II study failed to meet its primary endpoint. We must then undertake additional Phase I or Phase II clinical trials that are adjusted to account for the cause or causes of the initial Phase II study's failure. Although we have already identified a number of possible reasons for the failure to demonstrate efficacy in the recent Phase II trial, and we have also developed a preliminary plan for new clinical studies, there can be no guarantee that we will be able to identify with certainty why our Phase II study failed to meet its primary endpoint and that we will be able to make the needed adjustments for further Phase II studies to be successful. There is also no guarantee that the FDA would approve Psoraxine(R) even if we deem additional clinical trials to be successful.

We have devoted most of our resources to the development of Psoraxine(R) and our business is dependent on its success. In the United States, the marketing of Psoraxine(R) depends on FDA approval of the product. Analyzing the Phase II study data and conducting additional Phase II clinical trials will delay FDA approval. We may also decide to discontinue further clinical trials of Psoraxine(R), which would prevent us from obtaining FDA approval. If we are not able to obtain FDA approval for Psoraxine(R), we would be unable to sell the product and we would have to identify new potential products to develop.

Recent and future changes in senior management and board composition may affect our ability to implement our business plan. In addition we only have one member of our Audit Committee.

On January 25, 2006, we accepted the resignation James Sharpe, effective as of December 31, 2005 with respect to his position as Chief Executive Officer, President and member of the Board of Directors. Michael Garone, our Chief Financial Officer, currently serves as the interim Chief Executive Officer and interim President. Mr. Sharpe is our third Chief Executive Officer and President to resign in an 18 month period. Our ability to implement our business strategy may be adversely affected if we continue to experience unplanned senior management changes in the future or if we are unable to successfully integrate our current and future senior management personnel into our organization.

Additionally there have been changes to the composition of our Board of Directors. In April 2006, we received an announcement from Fabien Pictet that he will be resigning as a member of the Board of Directors. Further, in December 2005, Steven Fulda resigned as a member of the Audit Committee and member of the Board of Directors. As a result of Mr. Fulda's resignation, we only have one member of the Audit Committee. Moreover, our Audit Committee does not contain a member that qualifies as a financial "expert" as defined by Item 401(e) of Regulation S-B of the Exchange Act.

One of our existing stockholders can exert control over us and may not make decisions that further the best interests of all stockholders.

SkyePharma owns approximately 39.8% of our outstanding common stock. As a result, SkyePharma may exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Furthermore, the interests of SkyePharma may not always coincide with our interests or the interests of other stockholders and accordingly, they could cause us to enter into transactions or agreements which we would not otherwise consider. In addition, this concentration of ownership may delay or prevent a merger or acquisition resulting in a change in our control might affect the market price of our common stock, even when such a change in control may be in the best interest of all stockholders.



We may not be successful in the development and commercialization of products.

We may not develop products that prove to be safe and effective, that meet applicable regulatory standards or that we can manufacture at reasonable costs or market successfully. Successful products will require significant development and investment, including testing, to demonstrate their safety and efficacy prior to their commercialization. We have not proven our ability to develop and commercialize products. We must conduct a substantial amount of additional research and development before any regulatory authority will approve our initial product candidate, Psoraxine(R). Our research and development and clinical trials may not confirm the safety and efficacy of our products, in which case regulatory authorities may not approve them. In addition, even if we successfully complete our research and development efforts, Psoraxine(R) may not perform in the manner we anticipate, and may not be accepted for use by the public.

Substantial additional funds and effort will be necessary for further development and commercialization of Psoraxine(R).

Our initial product candidate, Psoraxine(R), will require the commitment of substantial resources to move it towards commercialization. Before obtaining regulatory approvals for the commercial sale of Psoraxine(R), we must demonstrate the safety and efficacy of our product candidate through preclinical testing and clinical trials. Conducting clinical trials involves a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product. If we or the U.S. Food and Drug Administration believe that our clinical trials expose participating patients to unacceptable health risks, we may suspend such trials.

We may encounter problems in our studies which will cause us or the FDA to delay or suspend the studies. Some of the factors that may delay our commencement and rate of completion of clinical trials include:

- ineffectiveness of the study compound, or perceptions by physicians that the compound will not successfully treat a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure of the FDA to approve our clinical trial protocols;
- slower than expected rate of patient recruitment;
- unforeseen safety issues; or
- government or regulatory delays.

The failure of future clinical trials may harm our business, financial condition and results of operations.



Our potential therapeutic products face a lengthy and uncertain regulatory process. If we do not obtain regulatory approval of our potential products, we will not be able to commercialize these products.

The FDA must approve any therapeutic product before it can be marketed in the United States. Before we obtain FDA approval of a new drug application or biologics license application, the product must undergo extensive testing, including animal and human clinical trials, which can take many years and requires substantial expenditure. Data obtained from such testing may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. In addition, changes in regulatory policy for product approval during the period of product development and regulatory agency review of each submitted new drug application may cause delays or rejections. We must devote a substantial amount of time and resources in the regulatory process in order to obtain regulatory approval of our initial product candidate, Psoraxine(R).

Because our initial product candidate, Psoraxine(R), involves the application of new technologies and may be used upon new therapeutic approaches, government regulatory authorities may subject this product to more rigorous review and may grant regulatory approvals more slowly for this product than for products using more conventional technologies. We have not received approval from the FDA to market or commercialize Psoraxine(R). The regulatory agencies of foreign governments must also approve any therapeutic product we may develop before the product can be sold in those countries. To date, although we have obtained regulatory approval for clinical testing of Psoraxine(R) in Venezuela, we have not sought, nor have we obtained, regulatory approval for the commercialization of Psoraxine(R) in Venezuela because, among other things, we do not have manufacturing facilities in that country and such facilities are required by regulatory authorities in Venezuela before granting commercial approval for a proposed drug.

Even after investing significant time and resources, we may not obtain regulatory approval for our product. If we do not receive regulatory approval, we cannot sell the product. Even if we receive regulatory approval, this approval may place limitations on the indicated uses for which we can market the product. Further, after granting regulatory approval, regulatory authorities subject a marketed product and its manufacturer to continual review, and discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer and manufacturing facility,

including withdrawal of the product from the market. In certain countries, regulatory agencies also set or approve prices.

Even if product candidates emerge successfully from clinical trials, we may not be able to successfully manufacture, market and sell them.

We have not successfully completed clinical trials of Psoraxine(R). If Psoraxine(R) emerges successfully from clinical trials and obtains regulatory approval, we will either commercialize products resulting from our proprietary programs directly or through licensing arrangements with other companies. We have no experience in manufacturing and marketing, and we currently do not have the resources or capability to manufacture, market or sell our products on a commercial scale. In order to commercialize Psoraxine(R) directly, we would need to develop or obtain through outsourcing arrangements the capability to manufacture, market and sell products. In addition, we currently do not have any agreements for the marketing or sale of any of our products and we may not be able to enter into such agreements on commercially reasonable terms, or at all.

We license and do not own our intellectual property. Any inability to protect our proprietary technologies adequately could harm our competitive position.



We license, and do not own, the intellectual property rights to Psoraxine(R). Dr. Jose Antonio O'Daly is the owner of the patent for Psoraxine(R). Under the terms of a license agreement and assignment of license agreement, we have the right to use any patent issued pursuant to Dr. O'Daly's patent application. We also have rights to other patents filed by Dr. O'Daly under the terms of our employment agreement with him. Our success will depend in part on our ability to obtain patents and maintain adequate protection of other intellectual property for our technologies and products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate our competitive advantage. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these foreign countries.

The patent positions of biotechnology companies, including our patent positions, involve complex legal and factual questions and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that we cover our proprietary technologies with valid and enforceable patents or we effectively maintain such proprietary technologies as trade secrets. We will apply for patents covering both our technologies and product candidates as we deem appropriate. However, we may fail to apply for patents on important technologies or products in a timely fashion, or at all, and in any event, the applications we do file may be challenged and may not result in issued patents. Any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. In addition, others may challenge or invalidate our patents, or our patents may fail to provide us with any competitive advantages. If we encounter challenges to the use or validity of any of our patents, resulting in litigation or administrative proceedings, we would incur substantial costs and the diversion of management in defending the patent. In addition, we do not control the patent prosecution of technology that we license from others. Accordingly, we cannot exercise the same degree of

control over this intellectual property as we would over technology we own.

We rely upon trade secrets protection for our confidential and proprietary information. We have taken measures to protect our proprietary information. These measures may not provide adequate protection for our trade secrets or other proprietary information. We seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose our proprietary information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

Many potential competitors which have greater resources and experience than we do may develop products and technologies that could make ours obsolete.

Companies in the biotechnology industry face rapid technological change in a rapidly evolving field. Our future success will depend on our ability to maintain a competitive position with respect to technological advances. Rapid technological development by others may result in our products and technologies becoming obsolete.

We face, and will continue to face, intense competition from organizations such as large biotechnology and pharmaceutical companies, as well as academic and research institutions and government agencies. Our competitors may include Biogen, Genentech/Xoma, Amgen, Wyeth, Abbott Laboratories and Novartis. These organizations may develop technologies that provide superior alternatives to our technologies. Further, our competitors may be more effective at implementing their technologies to develop commercial products.



Any products that we develop through our technologies will compete in multiple, highly competitive markets. Many of the organizations competing with us in the markets for such products have greater capital resources, research and development and marketing staffs, facilities and capabilities, and greater experience in obtaining regulatory approvals, product manufacturing and marketing. Accordingly, our competitors may be able to develop technologies and products more easily, which would render our technologies and products obsolete and noncompetitive.

If we lose our key personnel or fail to attract and retain additional personnel, we may be unable to discover and develop our products.

We depend on the services of Dr. Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer, and Michael Garone, interim Chief Executive Officer, interim President and Chief Financial Officer, the loss of whose services would adversely impact the achievement of our objectives. To execute our business plan fully it is essential that we retain these executives. In addition, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. Although we believe we can successfully attract and retain qualified personnel, we face intense competition for experienced scientists. Failure to attract and retain skilled personnel would prevent us from pursuing collaborations and developing our products and core technologies to the extent otherwise possible.

Our planned activities will require additional expertise. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing management personnel. The inability to acquire or develop this expertise could impair the growth, if any,

of our business.

If we face claims in clinical trials of a drug candidate, these claims will divert our management's time and we will incur litigation costs.

We face an inherent business risk of clinical trial liability claims in the event that the use or misuse of Psoraxine(R) results in personal injury or death. We may experience clinical trial liability claims if our drug candidates are misused or cause harm before regulatory authorities approve them for marketing. Although, we currently maintain clinical liability insurance coverage, it may not sufficiently cover any claims made against us and may not be available in the future on acceptable terms, if at all. Any claims against us, regardless of their merit, could strain our financial resources in addition to consuming the time and attention of our management. Law suits for any injuries caused by our products may result in liabilities that exceed our total assets.

Some of our existing stockholders can exert control over us and many not make decisions that further the best interests of all stockholders.

Our officers, directors and principal stockholders (greater that 5% stockholders) together control approximately 77.7% of our outstanding common stock. As a result, these stockholders, if they act individually or together, may exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders and accordingly, they could cause us to enter into transactions or agreements which we would not otherwise consider. In addition, this concentration of ownership may delay or prevent a merger or acquisition resulting in a change in control of us and might affect the market price of our common stock, even when such a change in control may be in the best interest of all stockholders.



The market price of our common stock may be highly volatile.

The market price of our common stock has been and will likely continue to be highly volatile. From the date trading of our common stock commenced until March 31, 2006, the range of our stock price has been between $0.02 and $7.15. Factors including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, government regulation, or developments or disputes relating to agreements, patents or proprietary rights may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by us, our stockholders, or the holders of warrants and options, could have an adverse effect on the price of our common stock.

A large number of shares of our common stock may be sold in the market, which may depress the market price of our common stock.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales might occur, could materially and adversely affect the market price of our common stock or our future ability to raise capital through an offering of our equity securities. We have an aggregate of 91,454,873 shares of our common stock outstanding. If all options and warrants currently outstanding to purchase shares of our common stock are exercised, there will be approximately 145,223,895 shares of our common stock outstanding.

Of the outstanding shares, up to 73,173,055 shares are freely tradable without restriction or further registration under the Securities Act, unless the shares are held by one of our "affiliates" as such term is defined in Rule 144 of the Securities Act. The remaining shares may be sold only pursuant to a registration statement under the Securities Act or an exemption from the registration requirements of the Securities Act. The sale and distribution of these shares may cause a decline in the market price of our common stock.

Our common stock qualifies as a "penny stock" under SEC rules which may make it more difficult for our stockholders to resell their shares of our common stock.

Our common stock trades on the OTC Bulletin Board. As a result, the holders of our common stock may find it more difficult to obtain accurate quotations concerning the market value of the stock. Stockholders also may experience greater difficulties in attempting to sell the stock than if it were listed on a stock exchange or quoted on the Nasdaq National Market or the Nasdaq Small-Cap Market. Because our common stock does not trade on a stock exchange or on the Nasdaq National Market or the Nasdaq Small-Cap Market, and the market price of the common stock is less than $5.00 per share, the common stock qualifies as a "penny stock." SEC Rule 15g-9 under the Exchange Act imposes additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as an "established customer" or an "accredited investor." This includes the requirement that a broker-dealer must make a determination on the appropriateness of investments in penny stocks for the customer and must make special disclosures to the customer concerning the risks of penny stocks. Application of the penny stock rules to our common stock could adversely affect the market liquidity of the shares, which in turn may affect the ability of holders of our common stock to resell the stock.

Item 2. Description of Property



We lease our executive offices and research laboratory located at 75 Passaic Avenue, Fairfield, New Jersey 07004. The yearly rent for such office and laboratory space is $110,400.

Item 3. Legal Proceedings

Neither we, nor any of our properties, are presently a party to any material legal proceeding, nor, to our knowledge, is any such proceeding threatened against us or any of our properties.

Item 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted for a vote of our shareholders during the fourth quarter of fiscal 2005.

PART II

Item 5. Market For Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the Over-the-Counter Bulletin Board ("OTC Bulletin Board") under the symbol ASTR.OB. The following table sets forth, for the periods indicated, the range of high and low bid quotations for shares of

our common stock as quoted on the OTC Bulletin Board. The reported bid quotations reflect inter-dealer prices, without retail markup, markdown or commissions, and may not necessarily represent actual transactions.

| 2004 | High | Low |
|---|---|---|
| First Quarter | $1.66 | $0.64 |
| Second Quarter | $1.46 | $1.04 |
| Third Quarter | $1.05 | $0.51 |
| Fourth Quarter | $0.85 | $0.42 |
| 2005 | | |
| First Quarter | $0.84 | $0.20 |
| Second Quarter | $0.40 | $0.20 |
| Third Quarter | $0.25 | $0.15 |
| Fourth Quarter | $0.16 | $0.02 |

Holders of Common Stock

As of March 31, 2006, there were approximately 89 record holders of our common stock.



Dividends

We have never paid or declared a cash dividend on our common stock. We intend, for the foreseeable future, to retain all future earnings for use in our business. The amount of dividends we pay in the future, if any, will be at the discretion of our Board of Directors and will depend upon our earnings, capital requirements, financial condition and other relevant factors.

Equity Compensation Plan Information

The following table provides information with respect to the equity securities that are authorized for issuance under our compensation plans as of December 31, 2005:

Equity Compensation Plan Information at December 31, 2005

| | Number of securities to be issued upon the exercise of outstanding options, warrants and rights (a) | Weighted-average exercise price of outstanding options, warrants and rights (b) | Nu r f c (e re |
|---|---|---|---|
| Equity compensation plans approved by securities holders | 1,454,000 | $0.26-$2.50 | |
| Equity compensation plans not approved by securities holders | 0 | 0 | |
| Total | 1,454,000 | $0.26-$2.50 | |

Recent Sales of Unregistered Securities

On March 31, 2006, the Company closed a private placement of securities from which it received proceeds of $250,000. In connection with such private placement, the Company issued to Blue Cedar, an accredited investor and currently a stockholder of the Company, (i) a convertible promissory note in the principal amount of $250,000, convertible into shares of the Company's Common Stock at $0.09 per share, and (ii) a warrant to purchase 2,777,778 shares of Common Stock. Lipworth Capital Limited acted as the placement agent in connection with this private placement. The securities offered and sold in this private placement were sold in reliance on an exemption from the registration requirements under Regulation D of the Securities Act of 1933.

On August 19, 2005, the Company closed a private placement of securities from which they received gross proceeds of approximately $2,000,000. The transaction consisted of the sale to one accredited investor, Blue Cedar, of units consisting of: (i) 18,181,818 shares of Common Stock, (ii) warrants to purchase over a 5-year period 18,181,818 shares of common stock with an exercise price of $0.165 and (iii) warrants to purchase over a 12-month period 12,121,212 shares of common stock with an exercise price of $0.165. The Company relied upon the exemption from registration provided under Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. The private placement was only made available to one "accredited investor" as defined in Rule 501 of



Regulation D and the required number of manually executed originals and true copies of Form D were and timely filed with the Securities and Exchange Commission. Lipworth Capital Limited acted as the placement agent in connection with the private placement. The Company paid an 8% fee to the placement agent and issued warrants to purchase 1,454,545 shares of common stock with an exercise price of $0.165, in connection with the financing in addition to other costs. Additionally, the Company granted Blue Cedar certain registration rights pursuant to a registration rights agreement, dated as of August 17, 2005, in connection with this transaction. The registration rights agreement required the Company to file a registration statement within approximately 30 days of the final closing of the private placement covering the resale of all shares included therein, as well as the shares underlying the warrants. Because a registration statement covering the resale of such shares was not filed or effective by December 31, 2005, the date specified in the agreement, the Company is subject to liquidated damages payments of $10,000 per month, being 0.5% of the aggregate purchase price plus 10% interest per annum to be paid on unpaid liquidated damages amounts until such time as a registration statement covering the resale of securities sold to Blue Cedar is declared effective by the Securities and Exchange Commission.

On June 4, 2005, the Company issued 20,000 options to a director. The options were issued with an exercise price of $0.28 and with a term of 10 years. The options shall vest over three years, with 25% vesting on the date of the grant and 25% vesting on the anniversary of the grant date until fully vested.

On April 11, 2005, the Company issued 50,000 options to a newly elected director. The options were issued with an exercise price of $0.26 and with a term of 10 years. The options shall vest over three years, with 25% vesting on the date of the grant and 25% vesting on the anniversary of the grant date until fully vested.

On February 2, 2005, the Company issued 20,000 options to a director. The

options were issued with an exercise price of $0.69 and with a term of 10 years. The options shall vest over three years, with 25% vesting on the date of the grant and 25% vesting on the anniversary of the grant date until fully vested.

In January 2005, the Company issued 100,000 shares of the Company's common stock along with 728,000 options to James Sharpe, the Company's former Chief Executive Officer and President. The options were issued with an exercise price of $0.70 with a term of ten years. The options vest over three years, with 25% vesting on the date of the grant and 25% vesting on the anniversary of the grant date until fully vested. Mr. Sharpe resigned as Chief Executive Officer, President and member of the Board of Directors as of January 25, 2006, with an effective resignation date of December 31, 2005.

In the first quarter of 2005 SkyePharma purchased the 11,160,000 shares of common stock from Mike Ajnsztajn and Gaston Liebhaber. Consequently, as of March 3, 2005 SkyePharma owned approximately 49.7% of the Company's outstanding common stock.

On December 10, 2004, we entered into an Employment Agreement with Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer. Pursuant to the terms of the Employment Agreement, we granted Dr. O'Daly options to purchase 728,000 shares of our common stock at an initial exercise price of $0.70 per share. The options were fully vested upon grant and expire in ten years.

On July 9, 2004, Steven Fulda, a former member of our Board of Directors, exercised options to purchase 25,000 shares of our common stock at $0.45 per share.

On July 2, 2004, we granted options to purchase 50,000 shares of our common stock at an exercise price of $1.00 per share to Samuel Barnett, one of our Directors. Twenty-five percent of the options were vested upon the date of grant, and options to purchase an additional 12,500 shares of our common stock will vest each year thereafter on the anniversary of the date of grant. The options will expire in four years.



In June 2004, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock to FPP Capital Advisors, which is controlled by Fabien Pictet, a member of our Board of Directors, in consideration for services valued at $75,000 that were rendered to us in negotiating a Call Option Agreement, dated January 12, 2004, between us and SkyePharma. The 150,000 warrants have an exercise price of $0.73 per share of common stock and expire five years from the date of issue. Under the Call Option Agreement, SkyePharma agreed that up to 12,500,000 shares of its common stock issued upon conversion of the Series A Convertible Preferred Stock will be subject to a call option, exercisable at our discretion upon completion of agreed upon milestones and ending on January 20, 2007. In the event we exercise the call option, the exercise price will be between $1.28 and $1.52 per share, depending on the date of exercise. We assigned to FPP Capital Advisors the right to purchase 1,250,000 shares of our common stock pursuant to the Call Option Agreement. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) of the Securities Act and Rule 506 of Regulation D under the Securities Act.

On January 20, 2004 and February 19, 2004, we sold to accredited investors units consisting of an aggregate of 10,459,866 shares of common stock and warrants to purchase 10,459,866 shares of common stock for an aggregate purchase price of approximately $5.23 million. The warrants have an exercise price of

$0.73 and expire in four years. We relied on the exemption from registration under Regulation D of the Securities Act. In July 2004, we filed a registration statement under the Securities Act covering the resale of the shares purchased and the shares issuable upon exercise of the warrants.

In connection with the private placements on January 20, 2004 and February 19, 2004, FPP Capital Advisors received a consulting fee of $261,496, warrants to purchase 418,394 shares of our common stock at $0.50 per share and warrants to purchase 418,394 shares of our common stock at $0.73 per share. The warrants expire in four years. FPP Capital Advisors will be paid an additional consulting fee equal to 5% of the proceeds we receive upon exercise of the warrants issued in the private placements. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) of the Securities Act and Rule 506 of Regulation D under the Securities Act.

On January 20, 2004, pursuant to an Omnibus Conversion Agreement, dated January 12, 2004, between us and SkyePharma, SkyePharma converted all of its 2,000,000 outstanding shares of Series A Convertible Preferred Stock into 25,000,000 shares of our common stock at a conversion price of $0.80 per share. As a result of this conversion, we no longer have any shares of preferred stock outstanding and SkyePharma no longer has rights as a preferred stockholder. We relied on the exemption from registration with the Securities and Exchange Commission provided under 4(2) of the Securities Act and Rule 506 of Regulation D under the Securities Act.

During the thirteen month period ending January 31, 2003, SkyePharma purchased 2,000,000 shares of our Series A Convertible Preferred Stock, par value $.001 per share pursuant to a Purchase Agreement dated as of December 10, 2001, at a purchase price of $10.00 per share, or an aggregate purchase price of $20.0 million. We sold these shares in reliance on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) and Rule 506 of Regulation D under the Securities Act.

On January 10, 2002, Mike Ajnsztajn, our former Chief Executive Officer and a former member of our Board of Directors, Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer, and Gaston Liebhaber, a former member of our Board of Directors, transferred, respectively, 175,000, 275,000 and 50,000 shares of our common stock owned by them to Manuel Tarabay for consulting services rendered by Mr. Tarabay in connection with their efforts to raise capital for our company. Messrs. Ajnsztajn, O'Daly and Liebhaber relied on the exemption from registration afforded by Section 4(2) of the Securities Act.



Item 6. Management's Discussion and Analysis or Plan of Operation

The following discussion of our financial condition and plan of operation should be read in conjunction with our financial statements and the related notes included elsewhere in this annual report on Form 10-KSB. This annual report contains certain statements of a forward-looking nature relating to future events or our future financial performance. We caution prospective investors that such statements involve risks and uncertainties, and that actual events or results may differ materially. In evaluating such statements, prospective investors should specifically consider the various factors identified in this annual report, including the matters set forth under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We disclaim any obligation to update information contained in any forward-looking statement.

Overview

We are a development stage biotechnology company engaged primarily in the research and development of treatments for immune system disorders and skin diseases. Our initial product candidate, Psoraxine(R), is a protein extract used for the treatment of the skin disease psoriasis.

Currently, we are engaged in the following activities to further our development efforts of our initial product candidate:

- Ongoing research and development of Psoraxine(R);
- Conducting clinical trials to obtain the approval of the United States Food and Drug Administration for the marketing of Psoraxine(R); and
- Development of the technology underlying Psoraxine(R) for the treatment of indications other that psoriasis, such as eczema, seborrheic dermatitis and leishmaniasis.

Fiscal year ended December 31, 2005 compared to fiscal year ended December 31, 2004.

For fiscal year ended December 31, 2005:

On August 19, 2005, the Company closed a private placement of securities from which they received gross proceeds of approximately $2,000,000. The transaction consisted of the sale to one accredited investor, Blue Cedar, of units consisting of: (i) 18,181,818 shares of common stock, (ii) warrants to purchase over a 5-year period 18,181,818 shares of common stock with



an exercise price of $0.165 and (iii) warrants to purchase over a 12-month period 12,121,212 shares of common stock with an exercise price of $0.165. The Company relied upon the exemption from registration provided under Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. The private placement was only made available to one "accredited investor" as defined in Rule 501 of Regulation D and the required number of manually executed originals and true copies of Form D were and timely filed with the Securities and Exchange Commission. Lipworth Capital Limited acted as the placement agent in connection with the private placement. The Company paid an 8% fee to the placement agent and issued warrants to purchase 1,454,545 shares of common stock with an exercise price of $0.165, in connection with the financing in addition to other costs. Additionally, the Company granted Blue Cedar certain registration rights pursuant to a registration rights agreement, dated as of August 17, 2005, in connection with this transaction. The registration rights agreement required the Company to file a registration statement within approximately 30 days of the final closing of the private placement covering the resale of all shares included therein, as well as the shares underlying the warrants. Because a registration statement covering the resale of such shares was not filed or effective by December 31, 2005, the date specified in the agreement, the Company is subject to liquidated damages payments of $10,000 per month, being 0.5% of the aggregate purchase price plus 10% interest per annum to be paid on unpaid liquidated damages amounts until such time as a registration statement covering the resale of securities sold to Blue Cedar is declared effective by the Securities and Exchange Commission.

In August 2005, the Board of Directors approved a resolution, subject to shareholder approval, to increase the authorized number of shares of common stock by 200,000,000 shares. The Company has not yet held a stockholders meeting

to approve such amendment.

For the fiscal year ended December 31, 2005, we had no revenue from operations and incurred operating expenses of $4,168,452 which consisted primarily of:

- Research and development costs of $2,510,521, including $1,635,461 that we incurred to complete our Phase II clinical study.

- General and administrative costs of approximately $1,657,931, including professional fees and our general corporate expenditures.

In December 2005, we received $306,921 in cash from the sale of a portion of our tax related net operating losses ("NOLS") under the State of New Jersey's Technology Business Tax Certificate Transfer Program. The program is an initiative adopted by the New Jersey State legislature that allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLS and defined research and development tax credits for cash.

In the fourth quarter of 2005 we recognized $83,000 as the fair value of the liquidated damages penalty provision payments in connection with the Registration Rights Agreement with Blue Cedar.

As a result, during the fiscal year ended December 31, 2005, we incurred a net loss of $3,914,159.

For fiscal year ended December 31, 2004:

On January 20, 2004 we closed a private placement from which we received gross proceeds of approximately $4.08 million. The transaction consisted of the sale to accredited investors of units consisting of 8,159,964 shares of common stock and warrants to purchase 8,159,964 shares of common stock. Concurrently with this transaction, SkyePharma converted all of its outstanding shares of Series A Preferred Stock into 25,000,000 shares of common stock at a reduced conversion price of $0.80 per share. In accordance with Statement of Financial Auditing Standard 84, "Induced Conversions of Convertible Debt, an Amendment of APB Opinion No. 26," we recorded this conversion transaction as a non-cash preferred stock dividend in January 2004 in the amount of $10,750,000.



On February 19, 2004, we held a second closing for our private placement from which we received gross proceeds of approximately $1.15 million. The transaction consisted of the sale to accredited investors of units consisting of 2,299,902 shares of common stock and warrants to purchase 2,299,902 shares of common stock. In connection with our private placements and the conversion of SkyePharma's Series A Preferred Stock, SkyePharma agreed that 12,500,000 shares of the common stock issued upon conversion will be subject to a right of repurchase by us under certain circumstances at a premium to the conversion price. We assigned the right to purchase 1,250,000 of these shares to FPP Capital Advisors as consideration for services it provided to us in negotiating the Series A Preferred Stock conversion by SkyePharma. Accordingly, we recorded a non-cash charge of $376,508 in June 2004 in connection with this assignment.

In February 2004, in connection with the private placement, FPP Capital Advisors received a consulting fee of $261,496, warrants to purchase 418,394 shares of our common stock at $0.50 per share and warrants to purchase 418,394 shares of our common stock. In June 2004, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock to FPP Capital Advisors in consideration for services rendered to us in

negotiating our right to repurchase 12,500,000 shares of common stock from SkyePharma.

For the fiscal year ended December 31, 2004, we had no revenue from operations and incurred operating expenses of $9,580,307 which consisted primarily of:

- Research and development costs of $7,689,060, including $2,360,000 that we incurred to conduct our Phase I and Phase II clinical studies, $1,007,500 for services provided by SkyePharma under our Service Agreement with them, amortization of approximately $714,288 of the technology option license under our Technology Access Option Agreement with SkyePharma as an intangible asset over its seven-year life, and a charge of $2,797,612 to record an impairment of the technology option license.

- General and administrative costs of approximately $1,860,844, including professional fees and our general corporate expenditures.

In December 2004, we received $293,461 in cash from the sale of a portion of our tax related NOLS under the State of New Jersey's Technology Business Tax Certificate Transfer Program. The program is an initiative adopted by the New Jersey State legislature that allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLS and defined research and development tax credits for cash.

As a result, during the fiscal year ended December 31, 2004, we incurred a net loss of $20,037,568, which also included a non-cash preferred stock dividend of $10,750,000.

The Next Twelve Months

At December 31, 2005 we had cash balances of $633, 468, which as of March 31, 2006 was substantially depleted but with the addition of funds from our sale of convertible notes and warrants, we estimate will last us through approximately May 2006, and no marketable securities. On March 31, 2006, the Company closed a private placement of securities from which it received proceeds of $250,000. In connection with such private placement, the Company issued to Blue Cedar, an accredited investor and currently a stockholder of the Company, (i) a convertible promissory note in the principal amount of $250,000, convertible into shares of the Company's Common Stock at $0.09 per share, and (ii) a warrant to purchase 2,777,778 shares of Common Stock. Lipworth Capital Limited acted as the placement agent in connection with this private placement. The securities offered and sold in this private placement were sold in reliance on an exemption from the registration requirements under Regulation D of the Securities Act of 1933. At March 31, 2006 the Company had cash balances of $289,607 which we estimate will last us through approximately May 2006 and no marketable securities.

Based on our current operating plan, we anticipate conducting the following activities and using our cash over the course of the next twelve months as follows:



- Our primary focus is to further development efforts of our initial product candidate, Psoraxine(R). In March 2005, the Company announced that the Phase II study of its novel immuno-stimulatory product for the treatment of Psoriasis did not meet the primary study endpoint upon completion of the treatment phase of the study. In the study, Psoraxine(R) was found to be safe and well-tolerated. Accordingly, we analyzed the data and

developed an hypothesis that may explain why we received these unexpected results. In this regard, we are implementing cost containment measures; realigning development activities to focus on such things as formulation, manufacturing, analytical protocols and potency; and we are testing the hypothesis to explain unexpected results and determine the best course for future development. We remain committed to Psoraxine(R) and its future development, and hope to see it return to Phase II clinical trials in 2006.

- We intend to implement our business plan and facilitate the operations of our company. The business plan will be implemented in phases: during the first phase we expect to test the hypothesis developed recently to assess causes for unexpected results in the Phase II trial. During the second phase, test results will be used to design and begin a new Phase II trial. We expect that we would be required to incur expenses of approximately $750,000 to third parties in connection with continuing development of Psoraxine(R).

- We will spend approximately $450,000 to pay management salaries and salaries of employees, a portion of which is treated as research and development expense.

- We also expect to expend approximately $700,000 for our general administrative and working capital requirements.

- In connection with the August 2005 Blue Cedar private placement, because a registration statement covering the resale of the Blue Cedar shares was not filed or effective by December 31, 2005, we are required to pay liquidated damages payments of $10,000 per month, being 0.5% of the aggregate purchase price plus 10% annum interest until such time as a registration statement covering the resale of securities sold to Blue Cedar is declared effective by the Securities and Exchange Commission.

- We will need to raise additional funds immediately to continue our operations for the period following the first quarter of 2006 and to fund any of the activities described above. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine(R). No assurance can be given that we will be able to obtain financing on terms that we find acceptable, or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders. Presently, neither our management nor our bankers have identified new sources of capital. If we do not obtain additional funds, we will likely be required to cease operations.

Item 7. Financial Statements

The financial statements required by this Item 7 begin at page F-1 of this annual report.

Item 8. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 8A. Controls and Procedures

(a) Evaluation of disclosure controls and procedures.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-KSB, our interim Chief Executive Officer, interim

President and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the



Exchange Act) are not effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

As a result of the audit of our 2005 financial statements by our independent auditors we have become aware of certain deficiencies that exist in the design and operation of our internal controls over financial reporting that our independent auditors consider to be material weaknesses under standards of the Public Company Accounting Oversight Board (PCAOB).

Our independent auditors identified certain errors in the financial statements in the current period that were not initially identified by the Company's internal control over financial reporting. The aggregate amount of these errors was material to our financial statements and therefore represent a material weakness in our internal control over financial reporting. Upon being notified of these errors we corrected the information included in the financial statements before such statements were filed with the Securities and Exchange Commission or disclosed publicly to any parties.

Management will review the system of internal controls and take steps to insure information required to be disclosed by the Company in reports that we file is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Committee's rules and forms.

(b) Changes in internal controls.

There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Item 8B. Other Information

None.

PART III

Item 9. Directors and Executive Officers of the Registrant

Code of Business Conduct and Ethics

We have a Code of Business Conduct and Ethics that applies to all directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. You can find our Code of Business and Ethics on our website by going to the following address: www.astralisltd.com. We will post any amendments to the Business Code of Conduct and Ethics as well as any waivers that are required to be disclosed by the rules of the Securities and Exchange Commission on our website.

Our Board of Directors has adopted Corporate Governance Guidelines and Charters for the Audit, Compensation and Nominating and Corporate Governance Committees of the Board of Directors. You can find these documents on our website by going to the following address: www.astralisltd.com.

You can also obtain a printed copy of any of the materials referred to above by contacting us at the following address: 75 Passaic Avenue, Fairfield, New Jersey 07004, Attention: Secretary.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors and persons who own more than 10% of our common stock ("Reporting Persons") to file reports of ownership and changes in ownership of our common stock with the SEC. Reporting Persons are required by SEC regulations to furnish us with copies of all reports they file pursuant to Section 16(a).

Based solely on our review of the copies of such forms received or written representations from Reporting Persons, we believe that with respect to the fiscal year ended December 31, 2005, all the Reporting Persons complied with all applicable filing requirements except that Fabien Pictet failed to timely file Forms 4 and Forms 5.

Directors and Executive Officers

The names, ages and positions of our current directors and executive officers are as follows:



| Name | Age | Position |
|---|---|---|
| Jose Antonio O'Daly, M.D., Ph.D. | 64 | Chairman of the Board of Directors and Chief Scientific Officer |
| Michael Garone | 47 | Chief Financial Officer, Interim Chief Executive Officer and Interim President |
| Michael Ashton | 60 | Director |
| Samuel Barnett, Ed.D. | 58 | Director |
| Fabien Pictet | 47 | Director |
| Gordon Schooley, Ph.D. | 59 | Director |
| Manuel Tarabay | 53 | Director |

There are no familial relationships among our directors and/or officers. Directors hold office until the next annual meeting of our stockholders or until their respective successors have been elected and qualified. Officers serve at the pleasure of the Board of Directors.

Jose Antonio O'Daly, M.D., Ph.D. Dr. O'Daly has served as our Chairman of the Board of Directors since November 2001, and was appointed our Chief Scientific Officer on December 22, 2004. From November 2001 to December 22, 2004, Dr. O'Daly served as our President of Research and Development. Dr. O'Daly is the sole founder of the Center for Research and Treatment for Psoriasis in Caracas, Venezuela and has served as its President since 1998. From 1972 to 1998, Dr. O'Daly served as Director and Head of Research of the Microbiology Center of the Venezuelan Institute of Scientific Investigations. Dr. O'Daly attended the Central University of Venezuela, Caracas, receiving his Doctorate of Medical Sciences in 1968. In 1971, Dr. O'Daly earned a Doctorate of Philosophy from the

Johns Hopkins University in Baltimore, Maryland. Dr. O'Daly is an honorary member of the Venezuelan Medical Academy.

Michael Garone. Mr. Garone has served as our Chief Financial Officer since February 21, 2005. From October 13, 2004 to February 21, 2005, Mr. Garone served as our Interim Chief Financial Officer. During 2004, Mr. Garone founded Gar-1 Business Advisory Services, L.L.C., an independent consulting company for information movement and management companies. From 1983 to 2003, Mr. Garone was employed by AT&T, Inc. where he held various positions of increasing responsibilities, including Chief Financial Officer of AT&T Alascom and Financial Planning Vice President, Broadband and Internet Services. Mr. Garone began his career in finance as an Over-the-Counter stock trader specializing in high technology start-up companies. Mr. Garone holds a B.A. in Mathematics from Colgate University and an M.B.A. from Columbia University.

Michael Ashton. Mr. Ashton has served as one of our Directors since January 2002. Mr. Ashton has 30 years of experience in the pharmaceutical industry, and since 1997 he has held the position of Chief Executive Officer of SkyePharma PLC, a London-based drug delivery technology provider. Prior to joining SkyePharma, Mr. Ashton served as Chairman and Chief Executive Officer of the U.S. subsidiary of Faulding, Australia's largest pharmaceutical companies. Mr. Ashton is a member of the Board of Directors of Transition Inc. Mr. Ashton holds a Bachelor of Pharmacy Degree from Sydney University and an M.B.A. from Rutgers University.



Samuel Barnett, Ed.D. Mr. Barnett has served as one of our Directors and a member of our audit committee since June 2004. In 1979, Mr. Barnett founded Barnett International, a consulting firm, and served as Chief Consultant from 1979 to 1999. From 1999 to 2000, Mr. Barnett served as Lead Partner of the Americas Pharmaceutical Practice of PricewaterhouseCoopers Consulting. From 2000 to 2005, he served as Lead Partner of the Americas Life Sciences Consulting Practice for IBM Business Consulting Services. Mr. Barnett holds a Bachelor's Degree from Wesleyan University and received both his Master's and Doctorate Degrees from Temple University.

Fabien Pictet. Mr. Pictet has served as one of our Directors since February 2002. Since 1998, Mr. Pictet has served as Chairman of Fabien Pictet and Partners, a London-based investment firm. Mr. Pictet has 20 years of experience in investing in emerging markets. During his 11 year tenure with Pictet and Cie, from 1986 to 1997, Mr. Pictet held various positions ranging from Manager responsible for U.S. equity investments to Partner responsible for all of the firm's institutional activities in Geneva, Zurich and London. Mr. Pictet holds a Bachelor's Degree in Economics from the University of San Francisco and a Master's Degree in International Management from American Graduate School of International Management. On April 19, 2006, Mr. Pictet announced that he will be resigning as a member of the Board of Directors. However, an effective date of Mr. Pictet's resignation has not yet been set.

Gordon Schooley, Ph.D. Dr. Schooley has served as one of our Directors and a member of our Medical Advisory Board since April 11, 2005. Dr. Schooley has over 33 years of experience in the pharmaceutical field, including extensive experience in clinical and product development. Since 1999, Dr. Schooley has served as Chief Scientific Officer of SkyePharma PLC. From 1989 to 1998, Dr. Schooley served as Vice President of Clinical and Regulatory Affairs for Alliance Pharmaceutical Corp. From 1987 to 1989, Dr. Schooley served as Vice President of Clinical and Regulatory Affairs for Newport Pharmaceuticals International, Inc. From 1979 to 1987, Dr. Schooley served as Director of Clinical Research, Biostatistics and Computing Services for Allergan

Pharmaceuticals. Dr. Schooley currently serves as a member of the Scientific Advisory Boards of Topigen Pharmaceuticals, Inc., Progen Ltd., and Seacology Foundation. Dr. Schooley holds a B.S. and an M.S. in Business and Statistics from Brigham Young University and received his Doctorate of Philosophy in Biostatistics from the University of Michigan School of Public Health.

Manuel Tarabay. Mr Tarabay has served as one of our Directors since August 19, 2005. Mr. Tarabay joined the Board in connection with the investment of $2 million by Blue Cedar. He serves as Blue Cedar's representative on the Board in accordance with the terms of Blue Cedar's investment which closed on August 19, 2005. Mr.Tarabay also acts as financial advisor to several investors who reside in the Middle East and Europe. During his 25 year career in Finance he has had various assignments throughout the world with Merrill Lynch, JPMorgan, Bankers Trust, Donaldson Lufkin Jenrette, and Credit Suisse First Boston. Mr. Tarabay holds a B. A. Degree in Mathematics (Computer Sciences) from Dartmouth College; a M. S. Degree in Computer Electronics Engineering from the Jesuit School of Engineering in Beirut; and an MBA Degree in Finance from Insead in Fountainbleau.



Advisors

Medical Advisory Board

James Leyden, M.D. Dr. Leyden has served as the Chairman of our Medical Advisory Board since November 2001. Dr. Leyden has been a Professor of Dermatology at the Hospital of the University of Pennsylvania in Philadelphia since 1983. He has served on the boards of many of the nation's key dermatological committees, including those of the American Academy of Dermatology and the Dermatology Foundation. Dr. Leyden has also served as a consultant to the U.S. Food and Drug Administration and the Federal Trade Commission, and to drug regulation agencies in England, Germany and Austria. Dr. Leyden has also assisted in the development, testing and commercialization of Accutane, Bactroban, Nizoral, Cleocin, Benzamycin, Benzaclin, Minocin and the use of bicarbonate to control body odor. Dr. Leyden holds a Bachelor's Degree from Saint Joseph's College and an M.D. from the University of Pennsylvania School of Medicine.

Gerald Krueger, M.D. Dr. Krueger has served on our Medical Advisory Board since December 2003. Dr. Krueger is a Professor of Dermatology at the University of Utah School of Medicine. Dr. Krueger consults for the U.S. Food and Drug Administration on psoriasis and serves on the executive committee of the Dermatology Foundation. In addition, he recently completed a ten-year term as Chairman of the Medical Advisory Board of the National Psoriasis Foundation. Dr. Krueger has been elected into the Alpha Omega Honor Society of Medicine. He has received the Taub International Award for psoriasis research, the American Skin Association Award for psoriasis research and the National Psoriasis Foundation's Lifetime Achievement Award and Founders Award.

Our Medical Advisory Board does not hold any formal meetings. However, management consults with the Medical Advisory Board from time to time. On April 11, 2005, we also appointed Dr. Schooley to serve on our Medical Advisory Board.

Audit Committee

The Audit Committee of our Board of Directors is an "Audit Committee" for the purposes of Section 3(a)(58) of the Securities Exchange Act of 1934. The Audit Committee recommends to the Board of Directors the independent public accountants to be selected to audit our annual financial statements, evaluates internal accounting controls, reviews the adequacy of the internal audit budget,

personnel and plan, and determines that all audits and exams required by law are performed fully, properly, and in a timely fashion. The sole member of the Audit Committee is Samuel Barnett. Currently, there is a vacancy on the Audit Committee as a result of Steven Fulda resigning on December 11, 2005 as a member of the Board of Directors and member of the Audit Committee. As a member of the Audit Committee, Mr. Fulda had served as the Audit Committee "financial expert" as defined by Item 401(e) of Regulation S-B of the Exchange Act. Samuel Barnett shall serve as the sole member of the Audit Committee until the Board of Directors appoints a member of the Board of Directors to fill the vacancy on the Audit Committee left by Mr. Fulda's resignation.

Other than in his capacity as a member of the Audit Committee, member of the Board of Directors or a member of any of our other Board committees, Mr. Barnett has not accepted from us, directly or indirectly, any consulting, advisory or other compensatory fee. In addition, Mr. Barnett does not have direct or indirect beneficial ownership of over 10% of our common stock or is one of our executive officers. Our Board of Directors has determined that Mr. Barnett is "independent" under NASD Rule 4200 and Item 7(d)(3)(iv) of Schedule 14A, promulgated under the Exchange Act.



Item 10. Executive Compensation.

The following table sets forth certain information regarding compensation paid by us and our predecessors during each of the last three fiscal years to our Chief Executive Officer and any other executive officer who received compensation greater than $100,000 during any of the last three fiscal years.

Summary Compensation Table

| | | Annual Compensation | |
|---|---|---|---|
| Name and Principal Position | Year | Salary ($) | Other Annual Compensation ($) |
| James Sharpe | 2005 | 231,000 | |
| Former President and Chief | 2004 | -- | -- |
| Executive Officer (1) | 2003 | -- | -- |
| | 2002 | -- | -- |
| Mike Ajnsztajn | 2004 | 109,875 | 2,437(4) |
| Prior Chief Executive Officer (2) | 2003 | 154,375 | 4,613 |
| | 2002 | 150,000 | 4,613 |
| Jose Antonio O'Daly, | 2005 | 217,482 | 34,283(6) |
| Chairman of the Board of Directors | 2004 | 188,487 | 41,004(5) |
| and Chief Scientific Officer (3) | 2003 | 158,750 | 73,740 |
| | 2002 | 150,000 | 56,671 |
| Michael Garone (7) | 2005 | 187,200 | -- |
| Chief Financial Officer, interim Chief Executive Officer and interim President | | | |

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(1) On January 25, 2006, we accepted the resignation of Mr. Sharpe, effective December 31, 2005 with respect to his position as a member of our Board of Directors and with respect to his position as our Chief Executive Officer and President.

(2) On July 28, 2004, we accepted the resignation of Mr. Ajnsztajn, effective immediately with respect to his position as a member of our Board of Directors and effective August 26, 2004 with respect to his position as our Chief Executive Officer.

(3) Dr. O'Daly became one of our employees on July 1, 2002. Prior to July 1, 2002, Dr. O'Daly provided services as a consultant to the company.

(4) For the fiscal year ended December 31, 2004, this amount includes $2,437 in health insurance premiums paid by us for Mr. Ajnsztajn's benefit.



(5) For the fiscal year ended December 31, 2004, this amount includes $8,707 in health insurance premiums paid by us for Dr. O'Daly's benefit, an automobile allowance of $5,729 and $26,568 for a furnished apartment.

(6) For fiscal year ended December 31, 2005, this amount includes legal fees paid by the Company for Dr. O'Daly's benefit in accordance with his employment contract.

(7) Mr. Garone became the Chief Financial Officer as of February 21, 2005. As of January 25, 2006, Mr. Garone was appointed by the Board of Directors to serve as interim Chief Executive Officer and interim President until the Board elects a new Chief Executive Officer and President to replace James Sharpe.

Employment Agreements

On December 22, 2004, we entered into an employment agreement with Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer. Under the terms of his employment agreement, Dr. O'Daly is entitled to an annual base salary of $231,000 payable in arrears in bi-monthly installments, less statutory deductions (the "Base Salary") and an annual bonus of up to 25% of his Base Salary and based upon achievement of such goals and subject to such additional terms as may be determined by the Board of Directors. As a member of our senior management team, Dr. O'Daly has been granted the option to purchase 728,000 shares of our common stock with an initial exercise price of $0.70 per share. The options are fully vested and have a term of ten years. In the event of a voluntary termination for "good reason" or if Dr. O'Daly is terminated following a change in control or without "cause," he generally will receive, among other things, the following severance benefits: (a) an amount equal to two times his annual Base Salary established for the fiscal year in which the date of termination occurs and (b) an amount equal to two times his annual bonus award established for the fiscal year in which his date of termination occurs. In the event of a voluntary termination by Dr. O'Daly without good reason, or if Dr. O'Daly is terminated by us for cause, he will receive the following severance benefits: (a) an amount equal to his Base Salary for one year and (b) an amount equal to one times his annual bonus award established for the fiscal year in which his date of termination occurs. The employment agreement includes certain non-competition and confidentiality provisions.

On January 27, 2005, we entered into an employment agreement with James Sharpe, our former Chief Executive Officer and President, pursuant to which Mr. Sharpe was entitled to (i) an annual base salary of $231,000 payable in arrears in bi-monthly installments, less statutory deductions ("Sharpe's Base Salary"); (ii) an annual bonus of up to 25% of Sharpe's Base Salary, based upon achievement of such goals and subject to such additional terms as were to be determined by the Board of Directors; and (iii) 100,000 shares of fully vested common stock issued on Mr. Sharpe's first day of employment. In addition, in

accordance with his employment agreement, Mr. Sharpe had been granted options to purchase 728,000 shares of common stock, of which options to purchase 182,000 shares had vested at the time of his resignation. Mr. Sharpe resigned from his positions at the Company, pursuant to the terms of the Separation Agreement, dated January 25, 2006. Pursuant to the terms of the Separation Agreement, Mr. Sharpe received a severance payment in the amount of $50,000. In addition, in accordance with the terms of the Separation Agreement, Mr. Sharpe had been granted options to purchase 182,000 shares of common stock which vested on January 27, 2006 at the market price as of such date and additional options to purchase 182,000 shares of common stock on January 27, 2007 at the market price as of such date.

On February 21, 2005, we entered into a consultant agreement with Michael Garone, whereby Mr. Garone was retained on a full-time, exclusive basis to serve as our Chief Financial Officer (the "Consultant Agreement"). As Chief Financial Officer, Mr. Garone is responsible for, among other things, our financial planning and funding. In addition, Mr. Garone leads and implements our long-term



strategy and vision to provide successful growth in value for our investors and shareholders. Under the terms of the Consultant Agreement, Mr. Garone is entitled to a monthly fee of at least $15,600. We have agreed to indemnify Mr. Garone against any claims that may arise as a result of the performance of his duties as our Chief Financial Officer under the consultant agreement and to include him, at our cost, as an insured party under our current directors' and officer' liability insurance policy. The term of the consultant agreement will continue until terminated by either party without cause upon 30 days written notice or with cause upon 10 days written notice.

On January 25, 2006 the Company's Board of Directors appointed Mr. Garone to serve as interim Chief Executive Officer and interim President until the Company's Board of Directors elects a new Chief Executive Officer and President to replace Mr. Sharpe.

None of our other executive officers receive compensation pursuant to any standard arrangement for their services as executive officers.

2001 Stock Option Plan

Our 2001 Stock Option Plan ("2001 Plan") was unanimously adopted by the Board of Directors on November 1, 2001 and approved by our stockholders at a special meeting held on November 1, 2001. The 2001 Plan provides for the issuance of 5,000,000 shares of common stock underlying stock options available for grant thereunder. The purpose of the 2001 Plan is to provide additional incentive to our directors, officers, employees and consultants who are primarily responsible for our management and growth. Each option will be designated at the time of grant as either an incentive stock option (an "ISO") or as a non-qualified stock option (a "NQSO"). As of December 31, 2005, options to purchase 1,454,000 shares of common stock have been granted under the 2001 Plan.

The 2001 Plan will be administered by our Board of Directors, or by any committee that we may in the future form and to which the Board of Directors may delegate the authority to perform such functions (in either case, the "Administrator").

Every person who at the date of grant of an option is an employee of ours or any affiliate of ours is eligible to receive NQSOs or ISOs under the 2001 Plan. Every person who at the date of grant is a consultant to, or non-employee

director of, ours or any affiliate of ours is eligible to receive NQSOs under the 2001 Plan.

The exercise price of a NQSO will be not less than 85% of the fair market value of the stock subject to the option on the date of grant. To the extent required by applicable laws, rules and regulations, the exercise price of a NQSO granted to any person who owns, directly or by attribution under the Code (currently Section 424(d)), stock possessing more than 10% of the total combined voting power of all classes of our stock or stock of any of our affiliates (a "10% Shareholder") will not be less than 110% of the fair market value of the stock covered by the option at the time the option is granted. The exercise price of an ISO will be determined in accordance with the applicable provisions of the Code and will not be less than the fair market value of the stock covered by the option at the time the option is granted. The exercise price of an ISO granted to any 10% Shareholder will not be less than 110% of the fair market value of the stock covered by the option at the time the option is granted.

The Administrator, in its sole discretion, will fix the term of each option, provided that the maximum term of an option will be ten years. ISOs granted to a 10% Shareholder will expire not more than five years after the date of grant. The 2001 Plan provides for the earlier expiration of options in the event of certain terminations of employment of the holder.



Options may be granted and exercised under the 2001 Plan only after there has been compliance with all applicable federal and state securities laws. The 2001 Plan will terminate within ten years from the date of its adoption by the Board of Directors.

If for any reason other than death or permanent and total disability, an optionee ceases to be employed by us or any of our affiliates (such event being called a "Termination"), options held at the date of Termination (to the extent then exercisable) may be exercised in whole or in part at any time within three months of the date of such Termination, or such other period of not less than thirty days after the date of such Termination as is specified in the Option Agreement or by amendment thereof (but in no event after the expiration date of the option (the "Expiration Date")); provided, however, that if such exercise of the option would result in liability for the optionee under Section 16(b) of the Exchange Act, then such three-month period automatically will be extended until the tenth day following the last date upon which optionee has any liability under Section 16(b) (but in no event after the Expiration Date).

The Board of Directors may at any time amend, alter, suspend or discontinue the 2001 Plan. Without the consent of an optionee, no amendment, alteration, suspension or discontinuance may adversely affect outstanding options except to conform the 2001 Plan and ISOs granted under the 2001 Plan to the requirements of federal or other tax laws relating to ISOs. No amendment, alteration, suspension or discontinuance will require shareholder approval unless (i) shareholder approval is required to preserve incentive stock option treatment for federal income tax purposes or (ii) the Board of Directors otherwise concludes that shareholder approval is advisable.

Board Composition

We currently have six directors, each serving a term until the next annual meeting of stockholders. Pursuant to the Blue Cedar Stockholder's Agreement, Blue Cedar may designate one director to our Board of Directors. Manuel Tarabay is Blue Cedar's initial and current designated director. The Blue Cedar Stockholder's Agreement will terminate upon the later of the Blue Cedar

Termination Date or August 15, 2008. The "Blue Cedar Termination Date" is the date on which Blue Cedar no longer beneficially owns, in the aggregate, at least 20% of the outstanding common stock of the Company. Further, pursuant to the Amended SkyePharma Stockholders' Agreement, our Board of Directors must include at least two independent directors and SkyePharma has the right to nominate one director. Michael Ashton is SkyePharma's initial and current nominated director. Until January 20, 2007, Dr. O'Daly has the right to nominate one director. The Amended SkyePharma Stockholders' Agreement will terminate upon the later of (i) the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock or (ii) January 20, 2007. Further, the Amended SkyePharma Stockholders' Agreement may be terminated by the mutual written consent of the parties.

Compensation of Directors

We reimburse all outside directors for travel and lodging expenses related to scheduled board meetings. Our Board of Directors authorized the following payments for non-executive directors during the fiscal year-ended December 31, 2005: $1,000 for each board meeting attended in person and $400 for each meeting attended by teleconference; an annual retainer of $4,000 paid to the Chairman of the Audit Committee; $1,000 paid to each Audit Committee member per financial filing; an annual retainer of $2,500 paid to the Chairman of the Compensation Committee; an annual retainer of $1,500 paid to each Compensation Committee member, other than the Chairman; an annual retainer of $3,000 paid to the Chairman of the Strategic Planning Committee; an annual retainer of $1,000 paid to each Strategic Planning Committee member, other than the Chairman; and $1,000 paid to each Strategic Planning Committee member for each half-day strategic planning meeting attended in person. In addition, each non-executive Director will receive a one-time grant upon election to the Board of stock options to purchase 50,000 shares of our common stock, vesting over a four-year period with the first 25% vesting on the date of grant, and an annual grant upon the anniversary of election to the Board of stock options to purchase 20,000 shares of our common stock, vesting over a four-year period with the first 25% vesting on the date of grant. Other than the foregoing, our directors do not receive compensation pursuant to any standard arrangement for their services as directors.



Indemnification Matters

Our Certificate of Incorporation eliminates the personal liability of directors to the fullest extent permitted by the provisions of paragraph (7) of subsection (b) of Section 102 of the General Corporation Law of Delaware. In addition, our Certificate of Incorporation includes provisions to indemnify our officers and directors and other persons against expenses, judgments, fines and amounts paid in settlement in connection with threatened, pending or completed suits or proceedings against those persons by reason of serving or having served as officers, directors or in other capacities to the fullest extent permitted by Section 145 of the General Corporation Law of Delaware.

Our bylaws provide the power to indemnify our officers, directors, employees and agents or any person serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise to the fullest extent permitted by Delaware law.

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth the names and beneficial ownership of our

common stock owned as of March 31, 2006, by (i) each of our directors, (ii) each person named in the Summary Compensation Table, (iii) all our directors and executive officers as a group, and, to the best of our knowledge, (iv) all holders of 5% or more of the outstanding shares of our common stock. Unless otherwise noted, the address of all the individuals and entities named below is care of Astralis Ltd. at 75 Passaic Avenue, Fairfield, NJ 07004.

| Name and Address | Number of Shares of Common Stock Beneficially Owned (1) | Percentage of Common Stock Owned |
|---|---|---|
| Dr. Jose Antonio O'Daly (2) (3) | 14,368,000 | 15.6% |
| Michael Ashton (4) | 36,413,900 | 39.8% |
| Samuel Barnett, Ph.D (5) | 130,000 | * |
| Fabien Pictet (6) | 3,677,794 | 3.9% |
| Gordon Schooley (7) | 12,500 | * |
| Manuel Tarabay (8) | 880,500 | * |
| Blue Cedar (9)<br>P.O. Box 546<br>28-30 The Parade<br>St. Helier, Jersey JE4 8X9<br>Channel Islands, United Kingdom | 54,040,404 | 42.4% |
| SkyePharma (3) (4)<br>105 Piccadilly<br>London W1J 7NJ<br>England | | |